

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

SHLOMO BEN-HAIM, NISSIM DARVISH,
YUVAL MIKA and MAIER FENSTER¹

Junior Party
(Patent 6,463,324),

v.

MORTON M. MOWER²

Senior Party
(Application 10/053,750).

Patent Interference No. 105,768 (SCM)
(Technology Center 3700)

Before RICHARD TORCZON, SALLY GARDNER LANE, and SALLY C.
MEDLEY, *Administrative Patent Judges.*

MEDLEY, *Administrative Patent Judge.*

DECISION –MOTIONS – Bd.R. 125

1 **A. Introduction**

2 The interference is before us to decide preliminary motions.

3 Ben-Haim seeks judgment against Mower on the basis that all of Mower's

¹ Ben-Haim real party in interest is Impulse Dynamics, N.V. (Paper 10).

² Mower real party in interest is MR3 Medical LLC. (Paper 4).

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1 involved claims 58-66 are unpatentable under 35 U.S.C. § 135(b)(1). (Ben-Haim
2 Motion 1; Paper 32). Ben-Haim also moves for no interference-in-fact. (Ben-
3 Haim Motion 2; Paper 31). Ben-Haim seeks to change the benefit accorded
4 Mower. (Ben-Haim Motion 4³; Paper 30). Ben-Haim moves for judgment against
5 Mower on the basis that all of Mower's involved claims 58-66 are unpatentable
6 under both the enablement and written description requirements of 35 U.S.C. §
7 112, ¶ 1. (Ben-Haim Motion 5; Paper 29).

8 Mower seeks to change the benefit accorded Ben-Haim. (Mower Motion 1;
9 Paper 25). Neither party filed responsive motions.

10 We GRANT Ben-Haim Motion 2; DISMISS Ben-Haim Motions 1, 4 and 5;
11 and DISMISS Mower Motion 1.

12 **B. The Interfering Subject Matter**

13 The interfering subject matter generally relates to a method for heart pacing
14 with modification of cardiac contraction. Count 1, the sole count, is Ben-Haim
15 claim 9. (Paper 1 at 4). Ben-Haim claim 9 is as follows:

16 A method for heart pacing with modification of cardiac
17 contraction, comprising the steps of:

18 (a) implanting at least one non-excitatory stimulation electrode
19 in each of a plurality of chambers of a subject's heart;

20 (b) conveying an excitatory electrical pulse to at least one of the
21 electrodes to pace the heart; and

22 (c) conveying a non-excitatory stimulation pulse of a magnitude
23 and at a timing at which it is unable to generate a propagating action

³ There is no Ben-Haim Motion 3. Ben-Haim's motions should have been consecutively numbered. SO ¶ 121.1.

1 potential to at least one of the electrodes to modify the cardiac
2 contraction.

3 **C. Ben-Haim Motion 2**

4 Ben-Haim moves for judgment of no interference-in-fact. (Paper 31). A
5 declaration of interference is presumed to be correct. *Bilstad v. Wakalopulos*, 386
6 F.3d 1116, 1120-21 (Fed. Cir. 2004). The burden of showing that the declaration
7 of interference is incorrect rests with the party challenging that decision by way of
8 a motion. *Id.* To be sufficient, a motion must provide a showing, supported with
9 appropriate evidence, such that, if unrebutted, it would justify the relief sought. As
10 set forth in Bd.R. 203(a), the test for no interference-in-fact is a one way
11 nonobviousness test. Ben-Haim need demonstrate that (1) no one of Mower's
12 involved claims 58-66 anticipates or renders obvious any one of Ben-Haim's
13 involved claims 2-5, 8-10, 12-15, 19, 21, 23, 25, 27, 29, 31, 33, 35 and 37-41 *or*
14 (2) no one of Ben-Haim's involved claims 2-5, 8-10, 12-15, 19, 21, 23, 25, 27, 29,
15 31, 33, 35 and 37-41 anticipates or renders obvious any one of Mower's involved
16 claims 58-66. Ben-Haim seeks to demonstrate that none of Ben-Haim's claims
17 anticipates or renders obvious any one of Mower's claims.

18 Ben-Haim claims 2-5, 8-10 and 12-15 are independent claims. Mower
19 claims 58-66 are independent claims. The parties focus on Mower independent
20 claim 62 and the most similar Ben-Haim claim, Ben-Haim claim 9, which forms
21 the count. (*See e.g.*, Paper 31 at 11:6-9 and Paper 38 at 7-8).

22 A chart comparing Ben-Haim claim 9 with Mower claim 62 is reproduced
23 below (emphasis added):
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Ben-Haim independent claim 9	Mower independent claim 62
<p>9. A method for heart pacing with modification of cardiac contraction, comprising the steps of:</p> <p>(a) implanting at least one non-excitatory stimulation electrode in each of a plurality of chambers of a subject's heart;</p> <p>(b) conveying an excitatory electrical pulse to at least one of the electrodes to pace the heart; and</p> <p>(c) conveying a non-excitatory stimulation pulse of a magnitude and at a timing at which it is unable to generate a propagating action potential to at least one of the electrodes to modify the cardiac contraction.</p>	<p>62. A method for heart pacing with modification of cardiac contraction, comprising the steps of:</p> <p>(a) implanting at least one non-excitatory stimulation electrode in each of a plurality of chambers of a subject's heart;</p> <p>(b) conveying an excitatory electrical pulse to at least one of the electrodes to pace the heart; and</p> <p>(c) conveying a non-excitatory <i>anodal</i> stimulation pulse as a first phase of a bi-phasic pacing pulse, the non-excitatory anodal stimulation pulse being of a magnitude and at a timing at which it is unable to generate a propagating action potential to at least one of the electrodes to modify the cardiac contraction.</p>

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As does Mower independent claim 62, each one of Mower's independent claims 58-66 includes a non-excitatory *anodal* stimulation pulse as a first phase of a bi-phasic pacing pulse. None of Ben-Haim's involved claims include a non-excitatory *anodal* stimulation pulse as a first phase of a bi-phasic pacing pulse. Ben-Haim argues that this difference is a patentable distinction between the Ben-Haim claims and the Mower claims.

We begin the analysis by addressing claim interpretation. Claim interpretation is a question of law, but the subordinate findings relating to proper

1 claim construction are issues of fact. Claim elements must be construed as they
2 would be understood by those skilled in the art. *See, e.g., Hoechst Celanese Corp.*
3 *v. B.P. Chems., Ltd.*, 78 F.3d 1575, 1578 (Fed. Cir. 1996).

4 Ben-Haim argues that Mower's involved claims replace the non-excitatory
5 pulse of Ben-Haim's involved claims with an excitatory biphasic pacing pulse;
6 that the two phases of the biphasic pulse operate as a single pulse to pace the heart;
7 and that the first phase, e.g., the non-excitatory phase of the biphasic pulse, has no
8 function in the absence of the second phase. (Paper 31 at 3:15-19). Ben-Haim also
9 argues that the required biphasic pacing pulse is separate from and in addition to
10 the excitatory electrical pulse in Mower's claims and thus Mower's claims require
11 two pacing pulses. (Paper 31 at 3:20 to 4:3).

12 Ben-Haim relies on the declaration testimony of Dr. Henriquez. Dr.
13 Henriquez is a professor of biomedical engineering and computer science and
14 serves as a director of the Duke University Center of Neuroengineering. He has
15 substantial experience in the relevant art since at least 1988. (Ex. 4004, ¶¶ 1-8).
16 Dr. Henriquez has sufficient qualifications to testify about the relevant state of the
17 art at the time of the invention.

18 Mower claim 62 recites conveying a non-excitatory anodal stimulation pulse
19 "as a first phase of a bi-phasic pacing pulse." Ben-Haim has sufficiently
20 demonstrated, with supporting evidence and in light of Mower's specification, that
21 the first phase of Mower's bi-phasic pacing pulse has no function and cannot be
22 separate from a second phase of the bi-phasic pacing pulse. Dr. Craig Henriquez
23 testified that one of ordinary skill in the art at the time of the invention would have
24 understood that both phases of Mower's biphasic pacing pulse comprise a single
25 waveform which acts to accomplish a singular goal of pacing the heart. (Ex. 4004,

¶ 113). Henriquez further testified that one of ordinary skill in the art would have understood Mower's claims to require a biphasic pacing pulse with two phases which operate as a single pulse to pace the heart and that the first phase of the biphasic pulse recited in Mower's claims has no function in the absence of the second phase. (FF 16; Ex. 4004, ¶ 208). Henriquez's testimony is credible and consistent with Mower's specification which describes the claimed invention in terms of using a biphasic pacing pulse that has a non-excitatory anodal phase and an excitatory cathodal phase that make up a single biphasic pacing pulse. (Ex. 4008, e.g., ¶¶ 2, 13 and 25).

Ben-Haim concludes that since the first phase of the bi-phasic pacing pulse has no function and cannot be separate from a second phase of a bi-phasic pacing pulse, the non-excitatory anodal stimulation pulse of Mower's claims cannot be conveyed without conveying the entire bi-phasic pulse. As such, Mower's claims, Ben-Haim argues, require conveying a bi-phasic pacing pulse that has two phases to the pulse – a non-excitatory anodal phase and an excitatory phase – both necessary for pacing the heart.

Mower agrees that all of its claims require applying a bi-phasic pacing pulse and that Ben-Haim's involved claims do not require this feature. (Paper 38 at 14, admitting Ben-Haim Facts 14, 18 and at 20, admitting Ben-Haim Fact 65).

However, Mower disagrees that the excitatory electrical pulse recited above, for example in Mower claim 62 (b), is not part of the biphasic pacing pulse, but rather a separate pacing pulse. (See, e.g., Paper 38 at 5:23 to 6:4 and at 12, denying Ben-Haim Fact 3). Mower does not direct us to evidence to support its proposed interpretation. Moreover, there is no indication in the claim language itself that the excitatory electrical pulse, recited as part (b) in Mower claim 62 above for

1 example, is part of the biphasic pacing pulse. There is no language in that claim
2 that connects or ties the excitatory electrical pulse to the biphasic pacing pulse.
3 We have also considered Mower's argument that Dr. Henriquez also interpreted
4 Mower's claims the way that Mower proposes. (Paper 38 at 5:23-28). However,
5 the argument is based on a misunderstanding of Dr. Henriquez's testimony. His
6 testimony that one of ordinary skill in the art would not have expected that pacing
7 the heart twice would be a substitute for using a non-excitatory pulse on the heart
8 goes to the question of nonobviousness and not claim interpretation.

9 For all of the above reasons, we hold that the broadest, most reasonable
10 interpretation of Mower's involved claims is the one proposed by Ben-Haim. The
11 Mower claims require two pacing pulses where one is a biphasic pacing pulse.

12 We now consider Ben-Haim's arguments of no interference-in-fact. Ben-
13 Haim has sufficiently demonstrated that none of its claims, if treated as prior art,
14 anticipate any of Mower's claims. (Paper 31 at 10-12). Mower acknowledges that
15 Ben-Haim claim 9 is broader in scope than Mower claim 62. Yet, Mower
16 concludes, without any explanation or without directing attention to evidence, that
17 "Ben-Haim Involved Claim 9 anticipates or, at least, renders obvious, Mower
18 Involved Claim 62." (Paper 38 at 8:15-16 and 8:25-26). Such a conclusory
19 statement is insufficient to rebut Ben-Haim's showing that not one of Ben-Haim's
20 claims anticipates any of Mower's claims.

21 In order to show that none of Ben-Haim's claims renders obvious any one of
22 Mower's claims, Mower must account for the underlying factual inquiries
23 including (1) the scope and content of the prior art; (2) the differences between the
24 claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4)
25 any objective evidence of unobviousness. *Graham v. John Deere Co.*, 383 U.S. 1,

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1 17 (1966). The factual inquiries are relevant and at issue for the nonobviousness
2 test.

3 Ben-Haim sufficiently addresses the level of skill in the art. Specifically,
4 Dr. Henriquez testified that one of ordinary skill in the art would have an advanced
5 degree, either a M.D. or Ph.D. degree in biomedical engineering or related area,
6 with 3-5 years of study and/or research in the area of cardiac electrophysiology
7 with knowledge of electrical stimulation. (Ex. 4004, ¶ 22). In its opposition,
8 Mower denies these facts. (Paper 38 at 20-21, denying Ben-Haim Fact 68).
9 However, Mower does not direct us to supporting evidence as to the level of skill
10 in the art. Accordingly, based on the record before us, one of ordinary skill in the
11 art would have had the skills and experiences as described in Dr. Henriquez's
12 testimony. As already explained, Dr. Henriquez is qualified to testify about the
13 relevant state of the art at the time of the invention.

14 The differences between Ben-Haim claim 9 and Mower claim 62 have been
15 discussed above in our claim interpretation discussion. Ben-Haim's claims do not
16 require conveying a bi-phasic pacing pulse. Nor do Ben-Haim's claims require
17 two pacing pulses. Mower's claims require these features. Thus, Ben-Haim's
18 claims are broader in scope than Mower's claims. Ben-Haim argues, with
19 supporting evidence, that one of ordinary skill in the art would not have substituted
20 a biphasic pacing pulse as recited in Mower's claims for a non-excitatory
21 stimulation pulse as recited in Ben-Haim's claims since there would no reasonable
22 expectation of success that the non-excitatory anodal stimulation phase of a bi-
23 phasic pacing pulse would modify cardiac output. (Paper 31 at 15:4-7).

24 In support of the argument, Dr. Henriquez testified that:

1 210. Taking the Ben-Haim Involved Claims as prior art, one of skill in
2 the art would not have thought, in 1996, that both the pacing and the
3 modification of cardiac output or contraction (as claimed by the Ben-
4 Haim Involved Claims) could be achieved by using a biphasic pacing
5 pulse instead of a non-excitatory pulse.
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7 211. One of skill in the art in the 1996 time frame would have
8 understood that for a non-excitatory pulse to have any effect on
9 contractility, the electrical signals would have had to be applied over a
10 substantial area of the heart and further not applied in a manner that
11 would be to assist in the pacing function.
12

13 And:
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15 215. One of skill in the art in 1996 would have understood that the
16 non-excitatory phase of the biphasic pacing pulse recited in Mower's
17 Involved Claims in the '768 interference would not propagate or
18 create a wave of action potentials across the heart muscle (only
19 excitatory pulses propagate) because it would be immediately
20 followed by a second pacing pulse that would create a wave of action
21 potentials across the heart.
22

23 216. One of skill in the art in 1996 would have believed that the non-
24 excitatory phase recited in Mower's biphasic pacing pulse limitation
25 would likely only affect the heart cells to which the pulse was directly
26 applied (by priming those cells to make them more receptive to pacing
27 at a lower voltage) and would not independently achieve some
28 additional functionality such as modifying cardiac contraction or
29 output.
30

31 We give substantial weight to Dr. Henriquez's testimony. One of ordinary
32 skill in the art at the time of the invention would not have expected the non-
33 excitatory anodal phase of a bi-phasic pacing pulse to modify cardiac contraction
34 or output. Accordingly, Ben-Haim has sufficiently demonstrated that Ben-Haim's
35 claims do not render obvious Mower's claims.

1 Mower has failed to sufficiently rebut Ben-Haim's showing of
2 nonobviousness. Mower's opposition as to the nonobviousness issue is brief and
3 consists of a single paragraph. (Paper 38 at 8). In that paragraph, Mower argues,
4 without directing attention to supporting evidence, that the application of a 'non-
5 excitatory anodal stimulation pulse' to one of the electrodes as recited in Mower
6 claim 62 is rendered obvious by the breadth of Ben-Haim claim 9. (Paper 38 at
7 8:20-24). The argument is unsupported and is misplaced. That a Ben-Haim claim
8 is broader than and may encompass a Mower claim is of no moment. At best, that
9 only demonstrates that Mower claim 62 anticipates Ben-Haim claim 9. The
10 argument does not address Ben-Haim's showing that Ben-Haim claim 9 does not
11 render obvious Mower claim 62.

12 Lastly, Mower's statement (Paper 38 at 8:25-26) that Ben-Haim claim 9
13 renders obvious Mower claim 62 is not supported by record evidence, but is based
14 on attorney argument. Attorney argument is not a substitute for supporting
15 evidence. *Meitzner v. Mindick*, 549 F.2d 775, 782 (CCPA 1977), *cert. denied*, 434
16 U.S. 854. *See also Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir.
17 1997) (Argument of counsel cannot take the place of evidence lacking in the
18 record). As a result, Mower has failed to sufficiently rebut Ben-Haim's showing
19 that there is no interference-in-fact.

20 For all of these reasons, Ben-Haim Motion 2 is GRANTED.

21 **D. Ben-Haim Motions 1 and 5**

22 Ben-Haim moves for judgment against Mower on the basis that all of
23 Mower's involved claims 58-66 are unpatentable under 35 U.S.C. § 135(b)(1).
24 (Paper 32). Ben-Haim also moves for judgment against Mower on the basis that
25 all of Mower's involved claims 58-66 are unpatentable under both the enablement

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1 and written description requirements of 35 U.S.C. § 112, ¶ 1. (Ben-Haim Motion
2 5; Paper 29).

3 Ben-Haim Motion 2 for no interference-in-fact is granted. The interference
4 will be terminated. As a result, there will not be a priority determination and we
5 dismiss Ben-Haim Motions 1 and 5. 35 U.S.C. § 135(a) (the Board “shall
6 determine questions of priority of the inventions and may determine questions of
7 patentability”); *See also Berman v. Housey*, 291 F.3d 1345, 1352 (Fed. Cir. 2002)
8 (explaining that the Board may, but need not, decide issues that have been fairly
9 raised and fully developed).

10 Ben-Haim Motions 1 and 5 are DISMISSED.

11 **E. Ben-Haim Motion 4 and Mower Motion 1**

12 Ben-Haim, through its Motion 4, moves to change the benefit accorded
13 Mower for the count. (Paper 30). Mower, through its Motion 1, moves to change
14 the benefit accorded Ben-Haim. (Paper 25).

15 Ben-Haim Motion 2 for no interference-in-fact is granted. The interference
16 will be terminated. As a result, there will not be a priority determination and
17 therefore there is no occasion to consider the benefit motions. Accordingly, we
18 dismiss Ben-Haim Motion 4 and Mower Motion 1.

19 **F. Order**

20 It is

21 **ORDERED** that Ben-Haim Motion 2 is GRANTED;

22 **FURTHER ORDERED** that Ben-Haim Motions 1, 4 and 5 are
23 DISMISSED; and

24 **FURTHER ORDERED** that Mower Motion 1 is DISMISSED.
25

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2 The Board has entered a Decision on Motions (Paper 136) granting Ben-
3 Haim Motion 2 for no interference-in-fact. Accordingly, it is

4 ORDERED that there is no interference-in-fact between the involved
5 claims of Mower's U.S. Application 10/053,750 and the involved claims of Ben-
6 Haim's U.S. Patent 6,463,324; and

7 FURTHER ORDERED that a copy of this judgment and the Decision on
8 Motions (Paper 136) be entered in the administrative records of Mower's U.S.
9 Application 10/053,750 and the involved claims of Ben-Haim's U.S. Patent
10 6,463,324.

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